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(54) Title: INTRAVASCULAR CATHETER WITH COMPOSITE REINFORCEMENT

(54) Titre: CATHETER INTRAVASCULAIRE A RENFORT COMPOSITERCEMENT

(57) Abstract

This invention is an intravascular catheter (10) that exhibits the combined features of superior flexibility, softness, radiopacity, and oval/kink resistance. The proximal region (14) of the shaft (12) includes an inner lubricous polymer layer (26), a reinforcement layer (32), and an outer layer (30). The reinforcement layer (32) may comprise a braid having one or more metallic helical members (42), and a plurality of mono-filaments (41), preferably formed of LCP. The polymer members of the braid provide improved flexibility, and softness in addition to high burst pressure. The metallic members of the braid provide improved radiopacity, and oval/kink resistance. The catheter (10) may also include one or more axial members disposed between the helical members that form the braid. The axial members (34) provide a number of advantages including maintaining one-to-one correspondence in axial manipulation; maintaining uniform flexibility in several planes of flexure; reducing the likelihood of causing a curling effect; uniformly increasing stiffness of the catheter; and increasing the burst strength of the catheter.

(57) Abrégé

L'invention concerne un cathéter intravasculaire (10) qui possède une combinaison de caractéristiques: de plus grandes souplesse, douceur et radio-opacité et une meilleure résistance à l'ovalisation et au vrillage. La région proximale (14) d'un arbre (12) comprend une couche polymère interne lubrifiante (26), une couche de renfort (32) et une couche externe (30). La couche de renfort (32) peut comprendre une tresse comportant deux ou plusieurs composants métalliques (42) et plusieurs filaments uniques (41), de préférence en LCP. Les éléments polymères de la tresse assurent une meilleure souplesse et une plus grande douceur, en plus d'une pression d'éclatement plus élevée. Les éléments métalliques de la tresse assurent une plus grande radio-opacité et une meilleure résistance à l'ovalisation et au vrillage. Le cathéter (10) peut aussi comprendre un ou plusieurs éléments axiaux disposés entre les éléments hélicoïdaux formant la tresse. Les éléments axiaux (34) offrent un certain nombre d'avantages, y compris le maintien de la correspondance un pour un lors des manipulations axiales, le maintien d'une flexibilité uniforme dans plusieurs plans de flexion, la réduction des risques d'un effet d'enroulement, l'augmentation uniforme de la rigidité du cathéter et l'augmentation de la pression d'éclatement.

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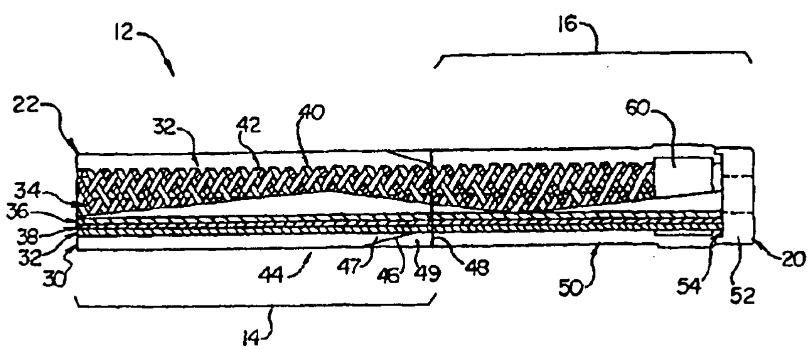

(57) Abstract

This invention is an intravascular catheter (10) that exhibits the combined features of superior flexibility, softness, radiopacity, and oval/kink resistance. The proximal region (14) of the shaft (12) includes an inner lubricous polymer layer (26), a reinforcement layer (32), and an outer layer (30). The reinforcement layer (32) may comprise a braid having one or more metallic helical members (42), and a plurality of mono-filaments (41), preferably formed of LCP. The polymer members of the braid provide improved flexibility, and softness in addition to high burst pressure. The metallic members of the braid provide improved radiopacity, and oval/kink resistance. The catheter (10) may also include one or more axial members disposed between the helical members that form the braid. The axial members (34) provide a number of advantages including maintaining one-to-one correspondence in axial manipulation; maintaining uniform flexibility in several planes of flexure; reducing the likelihood of causing a curling effect; uniformly increasing stiffness of the catheter; and increasing the burst strength of the catheter.

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Description

INTRAVASCULAR CATHETER WITH COMPOSITE REINFORCEMENT

Field of the Invention

The present invention generally relates to intravascular catheters. More specifically, the present invention relates to intravascular catheters having reinforcement.

Background of the Invention

Intravascular catheters are used in a wide variety of relatively non-invasive medical procedures. Such intravascular catheters may be used for diagnostic or therapeutic purposes. Generally, an intravascular catheter allows a physician to remotely perform a medical procedure by inserting the catheter into the vascular system of the patient at a location that is easily accessible and thereafter navigating the catheter to the desired target site. By this method, virtually any target site in the patient's vascular system may be remotely accessed, including the coronary, cerebral, and peripheral vasculature.

The distance between the access site and the target site is often in excess of 100 cm. The inside diameter of the vasculature at the access site is often less than 2 cm, and the inside diameter of the vasculature at the target site is often less than 0.5 cm. Accordingly, intravascular catheters must be relatively long and thin. Furthermore, in order to navigate through the patient's tortuous vascular system, intravascular catheters must be very flexible. It is also desirable that intravascular catheters be relatively soft in order to minimize the probability of damaging vascular tissue.

Intravascular catheters typically have a radiopaque portion and are guided through the patient's vascular system with the assistance of x-ray fluoroscopy. A physician may manipulate the proximal end of the catheter and fluoroscopically monitor the corresponding movement of the distal end of the catheter. As such, it is desirable that intravascular catheters be sufficiently radiopaque along their length and particularly at their distal end such that the physician is able to clearly monitor the progress of the catheter as it is being advanced from the vascular access site to the vascular target site.

After the intravascular catheter has been navigated through the patient's vascular system with the distal end thereof adjacent the target site, the catheter may be

used for various diagnostic and/or therapeutic purposes. Frequently, diagnostic and therapeutic techniques require the infusion of fluids through the catheter. For example, it may be desirable to inject radiopaque contrast media through the catheter to provide enhanced fluoroscopic visualization for diagnostic purposes, or to inject pharmaceutical solutions (i.e., drugs) to the target site for therapeutic purposes. In order to maintain a fluid path, it is desirable that intravascular catheters be sufficiently resistant to kinking. In addition, because such fluids are delivered under pressure, it is also desirable that intravascular catheters be sufficiently resistant to bursting.

To satisfy some of these desirable features, prior art intravascular catheters have utilized a reinforcement structure such as a braid or coil disposed between an inner tubular polymer layer and an outer tubular polymer layer. A braid reinforcement structure may offer high resistance to bursting and may improve the integrity of connections between individual shaft segments. However, a braid reinforcement structure may offer limited resistance to ovaling, which is a precursor to kinking. A coil reinforcement structure, by contrast, may provide adequate resistance to ovaling and kinking, but may not sufficiently enhance the integrity of connections between individual shaft segments.

As such, it is desirable to provide a catheter that offers high resistance to bursting, improves the integrity of connections between individual shaft segments, and provides substantial resistance to ovaling and kinking.

Some types of prior art intravascular catheters also utilize longitudinal or axial members to impart stiffness to the catheter shaft. For example, U.S. Patent No. 5,057,092 to Webster discloses an intravascular catheter having a braid reinforcing mesh and longitudinal warp members. The longitudinal warp members are intended to provide increased bending stiffness and thus permit reductions in the wall thickness and/or softer materials for the inner and outer tubes. The warp members are interwoven with the braid such that warp members alternate under or over the braid mesh. Because the braid reinforcing mesh is disposed between an inner polymeric layer and an outer polymeric layer, portions of the longitudinal warp members are disposed between the braid reinforcing mesh and the adjacent polymeric layer.

With this arrangement, the adjacent polymeric layer may conform to the longitudinal warp members so as to create radial protrusions running the length of the

catheter. A protrusion along the inside surface of the catheter may not be desirable because it may create friction or bias with devices inserted therein (e.g., guidewires). A protrusion along the outside surface of the catheter may not be desirable because it may create friction, bias or prevent adequate sealing with devices that the catheter is inserted into (e.g., introducer sheaths, compression fittings, etc.).

Also with this arrangement, the adjacent polymeric layer may become fixed to the longitudinal warp members as it conforms thereto. Fixing the longitudinal warp members to the adjacent polymeric layer may not be desirable because it may limit relative movement and flexure therebetween. Limiting relative movement and flexure may cause excessive stiffness in one or more planes of flexure. This may cause difficulties in manipulating and navigating the catheter through tortuous vasculature, which is clearly undesirable.

Accordingly, it is also desirable to provide a catheter having the advantages of a longitudinal or axial member without creating a protrusion and without fixing the axial member to the adjacent polymeric layer.

Summary of the Invention

The present invention addresses these desired features by providing an intravascular catheter that exhibits the combined features of superior flexibility, softness, radiopacity, durability, high burst strength, and oval/kink resistance.

An intravascular catheter in accordance with one embodiment of the present invention includes an elongate shaft having a proximal region, a distal region and a lumen extending therethrough. The proximal region of the shaft includes an inner lubricious polymer layer, a reinforcement layer and an outer layer. The reinforcement layer comprises a braid having at least one metallic member and a plurality of polymer members wherein each polymer member comprises a plurality of monofilaments. The monofilaments may be made of LCP having a substantially circular cross-section and may be fused together or held together statically. The monofilaments may be arranged side-by-side to collectively define a flat cable that may be twisted along the length of the shaft. The metallic member(s) may be made of a highly radiopaque material. The braid reinforcement provides high burst strength and durability. The polymer members of the braid provide enhanced flexibility and softness, and the metallic members(s) of the braid provide enhanced radiopacity and

resistance to ovaling and kinking. These combined features are not found in the prior art.

An intravascular catheter in accordance with another embodiment of the present invention includes an elongate shaft having a proximal region, a distal region and a lumen extending therethrough. The proximal region of the shaft includes an inner lubricious polymer layer, a reinforcement layer and an outer layer. The outer layer includes a proximal portion made of a first material having a first durometer, and a distal portion made of a second material having a second durometer less than the first durometer. The reinforcement layer comprises a braid having one or more metallic members and a plurality of polymer members wherein each polymer member comprises a plurality of monofilaments. The distal region of the shaft includes a radiopaque marker band surrounding the reinforcement layer and an atraumatic tip layer surrounding the radiopaque marker band and the reinforcement layer. The tip layer is made of a third material having a third durometer less than the second durometer. The tip layer includes a distal portion that extends beyond the distal ends of the inner layer and the reinforcement layer to form an atraumatic soft distal tip.

An intravascular catheter in accordance with yet another embodiment of the present invention includes a braid reinforcement with one or more axial wires or fibers disposed between the helical members that form the braid. The axial member(s) prevent elongation of the shaft of the catheter thereby maintaining one-to-one correspondence in axial manipulation of the catheter, even when the shaft is placed in tension. By placing the axial member(s) between the helical members, the axial member(s) do not create a protrusion on either side of the braid. In addition, the axial member(s) do not become fixed to any polymer layer adjacent the braid. Thus, this embodiment of the present invention maintains the benefits of axial member(s), but without creating the undesirable effects of friction caused by an axial protrusion and without creating the undesirable effects of limited flexure caused by an adjacent polymer layer becoming fixed to the axial member(s).

In addition to avoiding the undesirable effects discussed above, this embodiment of the present invention provides several other benefits by optionally utilizing a plurality of axial members. First, by equally spacing the axial members about the circumference of the catheter, the shaft maintains uniform flexibility in

several planes of flexure thereby facilitating precise control of the catheter as it is navigated through tortuous vasculature. Second, as compared to a single axial member, uniformly spacing the axial members about the circumference of the catheter reduces the likelihood of causing the catheter to curl when the lumen of the catheter becomes clogged and the catheter is pressurized. Third, the strength of the connections between adjacent shaft segments is increased significantly. Fourth, the stiffness of the catheter may be uniformly increased thereby potentially reducing the profile of the catheter by allowing the wall thickness and/or hardness of the polymer layers to be reduced. Fifth, the burst strength of the catheter may be significantly increased by virtue of the axial members limiting radial expansion of the shaft.

The axial members are preferably uniformly spaced about the circumference of the shaft. Virtually any number of axial members may be utilized, depending on the particular characteristics desired. For example, four or eight axial members may be utilized wherein the axial members are uniformly spaced apart by 90° or 45°, respectively, about the circumference of the shaft. In addition, only a portion of the shaft may include a plurality of axial members. For example, the distal shaft portion may have fewer axial members than the proximal shaft portion such that the distal shaft portion is more flexible. The axial members may comprise a polymeric material, a metallic material or a combination thereof. If a polymeric material is utilized, then each member may comprise a plurality of monofilaments such as LCP. The monofilaments may be held together statically thereby eliminating the need for a binding material that might otherwise add to the profile of the members. To further minimize profile, the monofilaments may be arranged side-by-side to collectively define a flat ribbon or cable.

The present invention also provides a method of making such a catheter. The manufacturing method includes the steps of braiding two or more helical members about one or more axial members such that the axial members are disposed between the helical members. The axial members are preferably uniformly spaced about the circumference of the shaft. The helical members may be braided over a carrier such as a mandrel that is later removed or a polymeric tubular member that becomes the inner layer of the catheter shaft. After the reinforcement layer is woven about the

carrier, another polymeric tubular member may be disposed about the reinforcement layer to become the outer layer of the catheter shaft.

Brief Description of the Drawings

Figure 1 is a plan view of an intravascular catheter in accordance with the present invention;

Figure 2 is a partially sectioned detailed view of the elongate shaft of the catheter illustrated in Figure 1;

Figure 3 is a cross-sectional view taken along line 3-3 in Figure 1;

Figure 4 is an alternative embodiment of the shaft;

Figures 5A and 5B are cross-sectional views of the polymer member of the reinforcement layer;

Figure 6 is a cross-sectional view taken along line 3-3 in Figure 1 illustrating another alternative embodiment of the shaft; and

Figure 7 is a fragmentary partially sectioned side view of the shaft illustrated in Figure 6.

Detailed Description of the Invention

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Figure 1 illustrates intravascular catheter 10 in accordance with the present invention. Catheter 10 includes an elongate shaft 12 having a proximal region 14 and a distal region 16. The catheter 10 includes a lumen 18 (as best seen in Figure 3) extending through the entire length of the elongate shaft 12 to an opening at the distal end 20 of the shaft 12. Catheter 10 may have a length of 80 to 150 cm and an outside diameter of approximately 3F.

A manifold 24 is connected to the proximal end 22 of the shaft 12 which includes an interior (not visible) in fluid communication with the lumen 18 of the elongate shaft 12. Manifold 24 includes a standard fitting 26 for connection to a fluid source such as a syringe. A strain relief 28 is disposed between the manifold 24 and the proximal end 22 of the shaft 12 in order to reduce the tendency of the shaft to kink therebetween. The proximal end 22 of the elongate shaft 12 may extend through the

strain relief 28 for connection to the manifold 24. Alternatively, the distal end of the strain relief 28 may be connected to the proximal end 22 of the elongate shaft 12 with the proximal end of the strain relief 12 connected to the manifold 24.

With either arrangement, the intravascular catheter 10 provides a fluid path from the fitting 26 of the manifold 24 to the distal end 20 of the elongate shaft 12 by way of the interior (not visible) of the manifold 24 and the lumen 18 of the elongate shaft 12. This intravascular catheter 10 may be advanced over a guide wire and used to deliver diagnostic and/or therapeutic fluids to a desired vascular target site using conventional techniques.

Figure 2 is a partially sectioned detailed view of the elongate shaft 12 of the intravascular catheter 10 illustrated in Figure 1. On the top portion of the shaft 12, the outer layer 30 has been removed to expose the reinforcement layer 32 and the axial member 34. On the bottom portion, the shaft 12 has been sectioned to illustrate the various layers 30, 32, 36, and 38 of the shaft 12.

Elongate shaft 12 includes a proximal region 14 and a distal region 16. Both the proximal region 14 and a portion of the distal region 16 include an inner lubricious polymer layer 36 surrounded by a reinforcement layer 32 which, in turn, is surrounded by an outer layer 30. The outer layer 30 may be loaded with a radiopaque contrast material such as barium sulfate, preferably loaded at 30% by weight. A tie layer 38 may be provided between the reinforcement layer 32 and the inner lubricious layer 36. Each of these layers are most clearly illustrated on the bottom portion of the shaft 12 shown in Figure 2 and the cross-sectional view taken along line 3-3 as shown in Figure 3.

Inner layer 36 is formed of a lubricious polymer such as PTFE or HDPE and preferably has a relatively thin wall to minimize profile. Inner layer 26 has an inside diameter sufficiently large to accommodate a conventional guidewire and to accommodate the delivery of fluids therethrough at a sufficient flow rate. For example, the inside diameter of the inner layer 36 may be approximately 0.027 inches and the wall thickness of the inner layer 36 may be approximately 0.0005 inches. The inner layer 36 may be formed, for example, by coating or extruding a lubricious polymer such as PTFE over a removable mandrel, or by using other known manufacturing techniques.

As mentioned previously, a tie layer 38 may be utilized to secure the reinforcement layer 32 to the inner lubricious layer 36. Tie layer 38 enhances the bond between the inner lubricious layer 36, the reinforcement layer 32, and the outer layer 30. Tie layer 38 also fills any micro-pores that may form in the inner layer 36 to thereby increase burst strength. Further, tie layer 38 maintains the position of the reinforcement layer 32 on the inner layer 36 during the manufacturing process. The thickness of the tie layer 38 may be approximately 0.0003 inches to reduce the corresponding increase in profile. An example of a suitable material for tie layer 38 is polyurethane, which may be coated onto the inner lubricious layer 36.

Reinforcement layer 32 comprises a braid including a plurality of helical polymer members 40 and one or more helical metallic members 42. For example, the reinforcement layer 32 in the form of a braid having a total of eight members may comprise six polymer members 40 and two metallic members 42. Those skilled in the art will recognize that the braid reinforcement layer 32 may vary in pattern, strand quantity, pick-count, etc., without departing from the scope of the present invention.

Each polymer member 40 comprises a plurality of monofilaments 41 to collectively define a cable 40A or 40B, illustrated in Figures 5A and 5B, respectively. Figures 5A and 5B show cross-sectional views of the polymer cables 40A and 40B of the reinforcement layer. Figure 5A illustrates a round cable 40A, and Figure 5B illustrates a flat cable 40B.

The monofilaments 41 may be unfused or fused together depending on the desired characteristics. Unfused monofilaments 41 may be held together statically thereby eliminating the need for a binding material that might otherwise add to the profile of the shaft 12. To further minimize profile, the monofilaments 41 may be arranged side-by-side to collectively define a flat ribbon or cable. If the monofilaments 41 are fused together, the polymer member 40 has mechanical characteristics similar to that of a solid rod. If the monofilaments 41 are not fused together, the polymer member 40 has mechanical characteristics similar to that of a cable. A cable, as opposed to a solid rod, is more flexible and is able to withstand more fatigue due to repeated bending. As such, a reinforcement layer 32 utilizing braided polymer members 40 comprising a plurality of unfused monofilaments 41 provide a shaft 12 that is more flexible and more durable. These features are

significant because the catheter 10 must be able to navigate tortuous vasculature and withstand harsh handling conditions.

The monofilaments 41 may be made of a liquid crystal polymer (LCP) available under the trade name VECTRAN. Each monofilament may have a circular cross-section having a diameter of 0.0007 inches. Each polymer member 40 may comprise two (2) to ten (10), and preferably five (5) monofilaments 41 which, as stated previously, may be fused or held together statically (i.e., unfused). If the monofilaments 41 are held together statically, the monofilaments of the polymer member 40 are typically arranged side-by-side to essentially define a flat cable 40B as shown in Figure 5B. It is possible, however, that the monofilaments be arranged in any manner to collectively define a flat cable 40B, a round cable 40A, or any other desired geometry.

Furthermore, if the monofilaments are arranged to collectively define a flat cable 40B, the flat cable 40B may be twisted along the length of the catheter shaft 12. Specifically, the flat cable 40B has a pair of major sides 43 and a pair of minor sides 45. Each of the major sides 43 faces the lumen 18 at various points along the length of the shaft 12. The flat cable may have random twists or a twist every 7.5 inches, depending on manufacturing conditions. Twisting the flat cable 40B may provide the advantage of improved guide wire movement due to ridges formed on the inside surface of the inner layer 36.

The metallic member 42 may be formed of stainless steel or a highly radiopaque material such as gold, tungsten, iridium, or an alloy thereof. If a plurality of metallic members 42 are utilized, one or more of the metallic members 42 may comprise stainless steel to provide superior strength and one or more metallic members 42 may comprise a highly radiopaque material to provide enhanced radiopacity. Although stainless steel provides higher radiopacity relative to most polymers, a more dense material such as those identified above are preferred for purposes of radiographic visualization. The metallic members 42 may have a rectangular cross-section or a circular cross-section, depending on the desired mechanical characteristics. Metallic member 42 may have a circular cross-section with a diameter of approximately 0.0016 inches to minimize profile.

An axial member 34 is disposed between the reinforcement layer 32 and the

tie layer 38 to provide enhanced resistance to elongation as the catheter 10 is removed from the patient's body. The axial member 34 may be an LCP flat cable, similar to cable 40B. The axial member 34 may be replaced by the axial member(s) 64 discussed with reference to Figures 6 and 7.

When the polymer members 40 and the metallic member(s) 42 are braided, the reinforcement layer 32 provides superior flexibility and softness by virtue of the polymer members 40 in addition to superior radiopacity and kink resistance by virtue of the metallic member(s) 42. These combined features are not found in prior art intravascular devices.

The proximal region 14 of shaft 12 includes an outer layer 30 formed by interrupted layer coextrusion (ILC) as described in U.S. Patent No. 5,622,665 to Wang, which is hereby incorporated by reference. The ILC portion 44 of outer layer 30 includes a proximal portion 47 formed of a relatively high durometer polymer and a distal portion 49 formed of a relatively low durometer polymer. By virtue of the ILC process, the proximal region 14 gradually transitions from the relatively high durometer polymer 47 to the relatively low durometer polymer 49. The transition between the relatively high durometer polymer 47 to the relatively low durometer polymer 49 is graphically illustrated by transition line 46. However, transition line 46 is typically not visible due to the intermixing of polymers during the ILC process. The ILC portion 44 may be formed of a suitable polymer such as polyether block amide having a wall thickness of approximately 0.0025 inches. For example, the proximal ILC portion 47 may be formed of PEBAX™ 7233, which has a durometer of 72D and the distal ILC portion 49 may be formed of PEBAX™ 3533 having a durometer of 35D.

The proximal region 14 of the outer layer 30 abuts the distal region 16 of the outer layer 30 at junction line 48. The distal region 16 of the shaft 12 includes a proximal portion 50 and a distal portion 52. Both the proximal portion 50 and the distal portion 52 of the distal region 16 may be formed of the same or different polymers which have a durometer less than the durometer of the distal portion 49 of the ILC section 44. The distal portion 52 of the distal region 16 may have the same or lower durometer than the durometer of the proximal portion 50. The proximal portion 50 and the distal portion 52 may be formed of a polyether block amide polymer such

as PEBAX™ 2533 having a durometer of 25D. The proximal portion 50 encapsulates the radiopaque marker band 60.

Radiopaque marker band 60 may be formed of gold, tungsten, iridium, or an alloy thereof. The radiopaque marker band 60 is disposed over the reinforcement layer 32 and may optionally be swaged onto the reinforcement layer 32. The radiopaque marker band 60 may optionally be adhesively secured to the reinforcement layer 32 or held in place by the encapsulating proximal portion 50.

The distal portion 52 of the distal region 16 abuts the distal ends of the various layers 36, 38, and 32 and forms a lap joint with proximal portion 50 along junction line 54. Junction line 54 between the proximal portion 50 of the outer layer 30 and the distal portion 52 is not present if the proximal portion 50 and the distal portion 52 are made of the same material, i.e., the proximal portion 50 and the distal portion 52 form a single unitary piece. Encapsulated marker band 60 may have a length of approximately 1.0 mm and may be positioned approximately 0.5 to 1.5 mm proximal of the distal end of the shaft 12. Distal portion 52 may extend approximately 0.5 to 1.0 mm beyond the distal end of the inner layer 36, tie layer 38 and reinforcement layer 32 to form an atraumatic soft tip.

Figure 4 is an alternate embodiment of the elongate shaft 12 illustrated in Figure 2. Specifically, Figure 4 illustrates an alternative arrangement of the outer layer 30 of the distal region 16 of the elongate shaft 12. Except as described herein, all aspects of the embodiment illustrated in Figure 4 are the same as those described with reference to the embodiment illustrated in Figure 2.

Distal region 16 includes a proximal portion 70 and a distal portion 72. Proximal portion 70 and distal portion 72 may be formed of the same materials as proximal portion 50 and distal portion 52, respectively, as described with reference to Figure 2. Distal portion 72 encapsulates the outer surface and distal face of the marker band 60. Distal portion 72 and proximal portion 70 are connected by a lap joint as defined by junction line 74. Junction line 74 between the proximal portion 70 and the distal portion 72 is not present if the proximal portion 70 and the distal portion 72 are formed of the same or similar materials. Distal portion 72 is approximately 2.5 to 3.0 mm in length and extends approximately 1.0 mm beyond the distal ends of the inner layer 36, the tie layer 38, and the reinforcement layer 32 to form an atraumatic

tip.

The elongate shaft 12, including the embodiment illustrated in Figure 2 and the embodiment illustrated in Figure 4, may be manufactured by a number of suitable manufacturing processes including the process described hereinafter. The inner layer 36 and the tie layer 38 may be obtained prefabricated from a suitable vendor, such as H.V. Technologies, and provided as discrete tubes or on a spool as a continuous tube. Axial member 34 is then disposed on the tube of inner layer 36 and tie layer 38. Optionally, the axial member 34 may be applied during the braiding step. The reinforcement layer 32 is then braided over the axial member 34 and the tube of inner layer 36 and tie layer 38. The braided subassembly is subsequently cut to the desired length. The marker band 60 is slid over the reinforcement layer 32 into position adjacent the distal end 20 of the elongate shaft 12. The proximal portion 50, 70 of the distal region 16 is slid over the reinforcement layer 32 adjacent the marker band 60. The proximal region 14 comprising a prefabricated ILC tube 44 is slid over the proximal end 22 of the elongate shaft 12. A heat shrink tube (e.g., FEP) is then placed over the shaft 12 components and the composite subassembly is pulled through a heated die. The die is heated to 380° - 430° F causing the components of the shaft 12 to be fused and compressed together by the combined heat and radial force. The heat shrink tube is then removed, exposing the completed shaft 12 subassembly. The manifold 24 and the strain relief 28 are then attached to the proximal end 22 of the elongate shaft 12 using conventional techniques. The catheter 10 is then tested for minimum performance criteria including burst pressure. The distal end 20 of the elongate shaft 12 is then trimmed to the desired length, and the distal portion 52, 72 of the distal region 16 is thermally fused thereto by, for example, inserting a mandrel into the lumen 18 and heating the tip 20 at 350° F for twenty-six (26) seconds. A lubricious coating is then applied to exterior of the catheter shaft 12.

As mentioned previously, the axial member 34 may be replaced with one or more axial members 64 as illustrated in Figures 6 and 7. Except as described hereinafter, the embodiment illustrated in Figures 6 and 7 is the same as the embodiment illustrated in Figure 2. Figure 6 is a cross-sectional view taken along line 3-3 in Figure 1, and Figure 7 is a fragmentary partially sectioned side view of the shaft 12. In Figure 7, the outer layer 30 has been removed to expose the braid

reinforcement layer 60 comprising helical members 62 (individually designated as 62A and 62B) and the axial members 64 (individually designated as 64A, 64B, 64C and 64D). The axial members 64 are disposed between the helical members 62A and 62B and are preferably uniformly spaced about the circumference of the shaft 12. In this embodiment, the inner lubricious polymer layer 36 is surrounded by the braid reinforcement layer 60 which, in turn, is surrounded by the outer layer 30. A tie layer 38 may be provided between the braid reinforcement layer 60 and the inner lubricious layer 36. This multi-layer construction may be used in either the proximal region 14 or both the proximal 14 and distal 16 regions, depending on the pushability, trackability, and other characteristics desired for each region.

As seen in Figures 6 and 7, the helical members 62 are interwoven to form a tubular braid. For purposes of illustration, only two helical members 62A and 62B in the form of two sets of LCP monofilaments are shown. Those skilled in the art will recognize that the braided helical members 62 may vary in material, number, pattern, pick-count, etc., without departing from the scope of the present invention. The helical members 62 may comprise a polymeric material, a metallic material or a combination thereof as discussed previously with regard to helical members 40 and 42. Polymeric helical members 62 provide superior flexibility and softness, metallic helical members 62 provide superior radiopacity and kink resistance, and a combination of polymeric and metallic helical members 62 provide a combination of these attributes.

One or more axial members 64 may be utilized. Virtually any number of axial members 64 may be utilized, depending on the particular characteristics desired. For example, four or eight axial members 64 may be utilized wherein the axial members 64 are uniformly spaced apart by 90° or 45°, respectively, about the circumference of the shaft 12. In addition, only a portion of the shaft 12 may include a plurality of axial members 64. For example, the distal shaft portion 16 may have fewer axial members 64 than the proximal shaft portion 14 such that the distal shaft portion 16 is more flexible.

Axial members 64 may comprise any of the same or similar structures and materials as helical members 62. As shown, the axial members 64 may each comprise a set of monofilaments which may be fused together or unfused depending on the

desired characteristics. Unfused monofilaments may be held together statically thereby eliminating the need for a binding material that might otherwise add to the profile of the shaft 12. To further minimize profile, the monofilaments may be arranged side-by-side to collectively define a flat ribbon or cable. Preferably, each axial member 64 comprises a plurality of LCP monofilaments arranged side-by-side as a flat cable, as best seen in Figure 6.

The axial members 64 limit elongation of the shaft 12 when the catheter 10 is placed in tension. The catheter 10 may be placed in tension when the catheter 10 is retracted in the proximal direction or withdrawn from a patient's vascular system and some resistance to movement is encountered. If the resistance to movement is encountered distal of the proximal end 22, the catheter shaft 12 is placed in tension. When significant tension is applied to the shaft 12, the axial members 64 limit elongation of the shaft. Further, the axial members 64 maintain one-to-one correspondence between axial manipulation of the proximal end 22 and axial movement of the distal end 20 of the shaft 12, even when the catheter 10 is placed in tension. By maintaining one-to-one correspondence in axial manipulation, the axial members 64 maintain precise control of the catheter 10.

By positioning the axial members 64 between the helical members 32A and 32B, the axial members 64 do not create a radial protrusion or become fixed to an adjacent polymer layer, both of which may create undesirable effects. Specifically, if the axial members 64 were placed over or under the helical members 62, radial protrusions may extend along the length of the inner layer 36 or the outer layer 30. Such protrusions along the inside surface of the catheter 10 may not be desirable because they may create friction or bias with devices inserted into the lumen 18. In addition, protrusions along the outside surface of the catheter 10 may not be desirable because they may create friction, bias, or prevent adequate sealing with devices that the catheter 10 is inserted into. By positioning the axial members 64 between the helical members 62A and 62B, no protrusions are formed thereby maintaining low friction and adequate sealing.

Further, if the axial members 64 were positioned under or over the helical members 62A and 62B, the inner layer 36 or the outer layer 30 may become fixed to the axial members 64, thereby limiting relative movement and flexure therebetween.

Limiting relative movement and flexure may cause excessive stiffness in one or more planes of flexure. This may cause difficulties in manipulating and navigating the catheter 10 through tortuous vasculature. By positioning the axial members 64 between the helical members 62A and 62B, relative movement therebetween is permitted thereby maintaining some amount of flexibility.

Utilizing even a single axial member 64 prevents axial elongation of the shaft 12 and thereby maintains one-to-one correspondence in axial manipulation of the catheter 10. Utilizing a plurality of axial members 64 provides a number of other advantages. By equally spacing the axial members 64 about the circumference of the shaft 12, the shaft 12 maintains uniform flexibility in several planes of flexure corresponding to the number of axial members used. The greater the number of axial members used, the greater number of planes of uniform flexibility. Uniform flexibility provides precise control of the catheter 10 as it is navigated through tortuous vasculature.

As compared to a single axial member, uniform spacing of the axial members 64 about the circumference of the shaft 12 also reduces the likelihood of causing the catheter to curl when the lumen 18 of the catheter 10 becomes clogged and the catheter 10 is pressurized. This may be encountered, for example, if the catheter 10 is utilized to deliver embolic material that unintentionally occludes the lumen 18. By reducing the likelihood of curling, the likelihood of causing trauma to the interior of the vessel wall is also reduced.

The axial members 64 also increase the strength of the connections between adjacent shaft segments and the burst strength of the shaft 12. The axial members further provide additional stiffness to the catheter shaft 12 such that the wall thickness and/or hardness of the polymer layers 30 and 36 may be reduced.

To provide a catheter 10 having one or more axial members 64 disposed between helical members 62, the catheter 10 may be made as discussed previously with some modifications to the braiding step. Although braiding helical members is well known in the art, positioning axial members between the helical members requires some modification to conventional braiding machines. For example, a conventional Steeger braiding machine may be modified to incorporate individual bobbin carriers that deliver the axial members 64 through a horn gear shaft. The axial

member 64 carriers are retrofitted onto the horn gear. With this arrangement, one of the helical member 62A carriers is allowed to pass under and the other helical member 62B carrier is allowed to pass over the axial members 64. The net result is a braid reinforcement structure 60 comprising two or more interwoven helical members 62, with one or more axial members 64 disposed therebetween.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

Claims

What is claimed is:

1. An intravascular catheter, comprising an elongate shaft having a proximal region, a distal region and a lumen extending therethrough, the proximal region including an inner lubricious polymer layer, a reinforcement layer and an outer layer, each layer having a distal end, the reinforcement layer comprising a braid having a metallic member and a plurality of polymer members wherein each polymer member comprises a plurality of monofilaments.

2. An intravascular catheter as in claim 1, wherein the monofilaments comprise LCP.

3. An intravascular catheter as in claim 2, wherein the monofilaments are arranged side-by-side to collectively define a flat cable.

4. An intravascular catheter as in claim 1, further comprising an axial member extending along the reinforcement layer.

5. An intravascular catheter as in claim 4, wherein the axial member comprises a plurality of monofilaments.

6. An intravascular catheter as in claim 5, wherein the axial member comprises a polymer.

7. An intravascular catheter as in claim 6, wherein the axial member comprises LCP.

8. An intravascular catheter as in claim 7, wherein the monofilaments of the axial member are arranged side-by-side to collectively define a flat cable having a first major side and a second major side, one of the major sides facing the lumen of the shaft.

9. An intravascular catheter as in claim 8, wherein the first major side faces

the lumen of the shaft for a first length and the second major side faces the lumen of the shaft for a second length.

10. An intravascular catheter as in claim 1, wherein the distal region includes a radiopaque marker band surrounding the reinforcement layer, and wherein the distal region includes an atraumatic tip layer surrounding at least a portion of the radiopaque marker band and at least a portion of the reinforcement layer, the tip layer including a distal portion that extends distally beyond the distal ends of the inner layer and the reinforcement layer.

11. An intravascular catheter, comprising an elongate shaft having a proximal region, a distal region and a lumen extending therethrough, the proximal region including an inner lubricious polymer layer, a reinforcement layer and an outer layer, each layer having a distal end, the outer layer including a proximal portion and a distal portion, the proximal portion of the outer layer comprising a first material having a first durometer, the distal portion of the outer layer comprising a second material having a second durometer less than the first durometer, the reinforcement layer comprising a braid having a metallic member and a plurality of polymer members wherein each polymer member comprises a plurality of monofilaments, the distal region of the shaft including a radiopaque marker band surrounding the reinforcement layer and an atraumatic tip layer surrounding at least a portion of the radiopaque marker band and at least a portion of the reinforcement layer, the tip layer including a distal portion that extends distally beyond the distal ends of the inner layer and the reinforcement layer, the tip layer comprising a third material having a third durometer less than the second durometer.

12. An intravascular catheter comprising an elongate shaft having a lumen extending therethrough, the shaft including an inner polymer layer, a reinforcement layer disposed about the inner layer and an outer polymer layer disposed about the reinforcement layer, the reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member and one or more axial members disposed between the first helical member and the second helical member.

13. An intravascular catheter as in claim 12, wherein the elongate shaft has a circumference and wherein the axial members are uniformly spaced apart about the circumference of the shaft.

14. An intravascular catheter as in claim 13, wherein four axial members are uniformly spaced apart by 90° about the circumference of the shaft.

15. An intravascular catheter as in claim 13, wherein eight axial members are uniformly spaced apart by 45° about the circumference of the shaft.

16. An intravascular catheter as in claim 12, wherein the elongate shaft includes a proximal portion and a distal portion, and wherein the distal shaft portion has fewer axial members than the proximal shaft portion.

17. An intravascular catheter as in claim 16, wherein the proximal shaft portion has the plurality of axial members and the distal shaft portion has one axial member selected from the plurality of axial members.

18. An intravascular catheter as in claim 16, wherein the axial members are movable relative to the inner and outer layers.

19. An intravascular catheter as in claim 16, wherein the inner and outer layers have respective inner and outer surfaces free of protrusions caused by the axial members.

20. An intravascular catheter as in claim 16, wherein the first and second helical members each comprise polymeric material.

21. An intravascular catheter as in claim 20, wherein the first and second helical members each comprise a plurality of monofilaments.

22. An intravascular catheter as in claim 21, wherein the axial members each comprise a polymeric material.

23. An intravascular catheter as in claim 22, wherein the axial members each comprise a plurality of polymeric monofilaments.

24. An intravascular catheter as in claim 23, wherein the monofilaments comprise LCP.

25. An intravascular catheter as in claim 24, wherein the monofilaments are arranged side-by-side to collectively define a flat ribbon.

26. An intravascular catheter comprising an elongate shaft having a reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member and one or more axial members disposed between the first helical member and the second helical member.

27. A method of making a portion of a shaft of an intravascular catheter, the method comprising the steps of:

braiding a first helical member and a second helical member about a carrier such that one or more axial members are disposed between the first and second helical members.

28. A method of making a portion of a shaft of an intravascular catheter as in claim 27, wherein the axial members are uniformly spaced about the circumference of the shaft.

29. A method of making a portion of a shaft of an intravascular catheter as in claim 28, wherein four axial members are uniformly spaced apart by 90° about the circumference of the shaft.

30. A method of making a portion of a shaft of an intravascular catheter as in claim 28, wherein eight axial members are uniformly spaced apart by 45° about the circumference of the shaft.

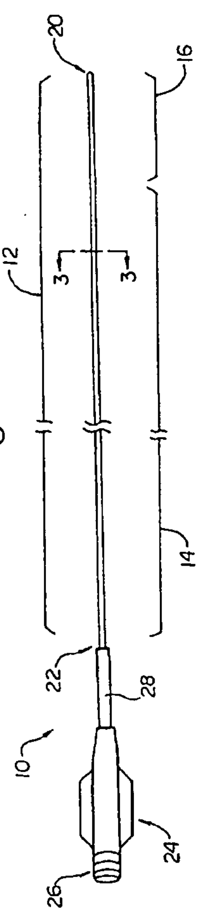
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Fig. 1

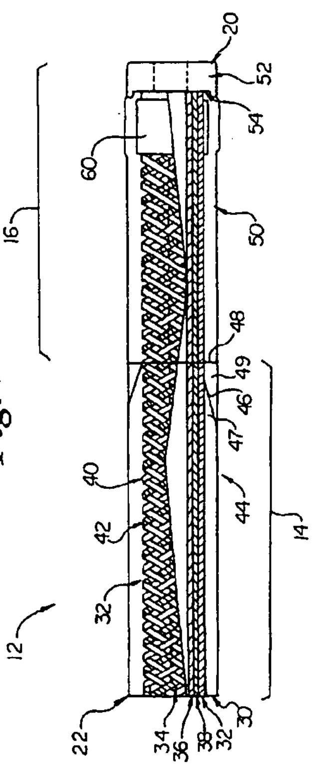
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Fig. 2

Fig. 3

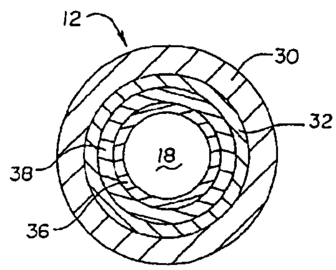


Fig. 4

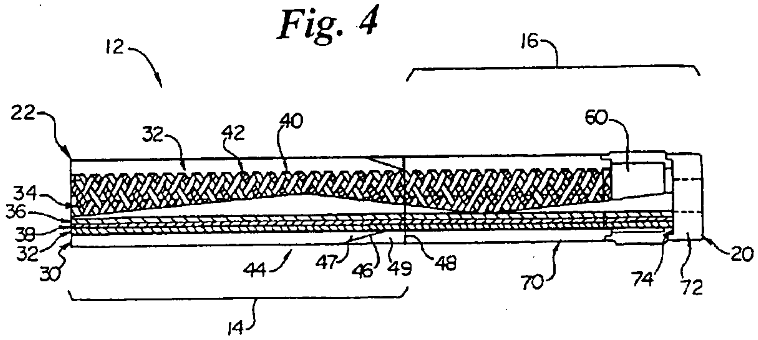


Fig. 5A

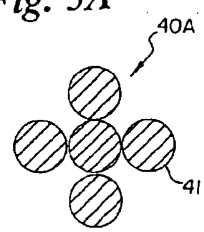


Fig. 5B

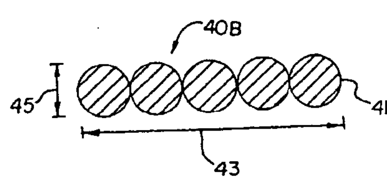


Fig. 6

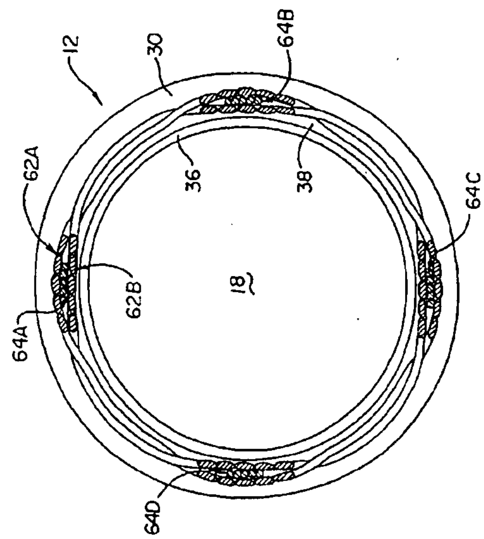
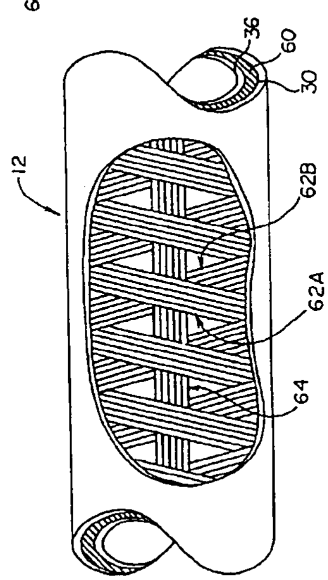


Fig. 7



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/01412

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) :A61M 25/00
US CL :604/282
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 604/264, 282, 523-529

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,702,373 A (SAMSON) 30 December 1997, entire document.	1-30
Y	US 5,454,795 A (SAMSON) 03 October 1995, entire document.	1-30
Y,P	US 5,947,940 A (BEISEL) 7 September 1999, entire document.	7, 8, 24, 25

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
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Date of the actual completion of the international search
25 MARCH 2000

Date of mailing of the international search report
21 APR 2000

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